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| 09/890,227 | 11/14/2001 | Hans-Dieter Borowsky | HHI-033US | 7538 |
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| LAHIVE & COCKFIELD 28 STATE STREET BOSTON, MA 02109 | | | PENDLETON, DIONNE | |
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| | | | 2615 | |

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,227

Applicant(s)

BOROWSKY ET AL.

Examiner

Dionne H. Pendleton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. A set of drawings in compliance with 37 CFR 1.121(d) are required in this application because drawings have been furnished in the PCT WO 00/45617 A3 only. While these drawings have been relied upon during examination of the immediate U.S. Application, the Applicant is required to file a set of drawings in the U.S. Application prior to the allowance of any claims. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The requested drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. **Claim 1** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Line 2 of claim 1 recites the passage "free of external moving operational elements" which is misdescriptive for the following reason:

In the Applicant's provided figure, sound tube **6** is *external* to cylindrical housing **2a,2b**, and *moves* with an applied rotational force, *operating* to transmit sound to the ear canal of the wearer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. **Claims 1 and 7** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Reiter et al. US 5,724,431** in view of **Gnecco US 5,640,457** and further in view of **Giannetti US 5,675,657**.

Regarding claim 1, *and as best understood with regard to the U.S.C. 112 second paragraph rejection above*, shown in **figure 4**, Reiter teaches a treatment device **62** for correcting impairments to hearing, comprising: an *essentially* cylindrically shaped portion (unlabeled) for insertion into the ear canal of the wearer, said cylindrically shaped portion reading on " comprising: an *essentially* cylindrically shaped housing"; as shown in **figures 4 and 5**, said cylindrical shaped housing (for insertion into the wearer's ear canal) is free of external moving operational elements, as claimed,

Additionally, in **figure 5**, Reiter teaches an embodiment wherein, when considering the entire housing of the hearing device, the volume control dial **60'** is replaced by an internally mounted screw driver adjustable knob **60''**. Since **figure 5**

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shows that by replacing the volume control knob **60'** of **figure 4**, with a screw driver adjustable knob **60''**, the operational element **60''** is no longer located externally of the device and will constitute an *internally* mounted knob **60''** which reads on "free of *external* moving operational elements";

Reiter teaches a battery compartment **32** and a sound exit opening (not labeled) inherently provided at the end of the cylindrical shaped housing which transmits sound into the ear canal of the wearer;

And a hole **50** for providing external access to the battery compartment, as claimed.

Reiter does not clearly teach that the housing is formed of metal and that said metal housing shields an electronics unit located therein against electromagnetic waves.

In **column 1, lines 13-19**, Gnecco teaches an invention for use in ITC and CIC devices, such as the device disclosed by Reiter, and further teaches in **column 3, lines 21-22**, that it is well known in the art to construct the housing of a treatment device such that it is formed of metal, and whereby the electronic units of the treatment device are shielded against electromagnetic waves. Therefore, it would have been obvious for one of ordinary skill in the art at the time of the invention to combine the teachings of Reiter and Gnecco, modifying the housing of Reiter such that it is constructed from metal and thereby shielding the internal units from electromagnetic interference, so as to provide a hearing device which is not adversely affected by radio signals.

The combined teachings of Reiter and Gnecco does not clearly teach that the battery compartment is provided with a ring magnet retaining means for retaining the batteries in the battery compartment.

Giannetti teaches a battery compartment comprising a cover **31** and a cup-like battery holder. Giannetti further teaches that a magnet **45** is affixed to said cover **31**, reading on “a ring magnet retaining means”. Although Giannetti teaches that the magnet **45** is located on the cover **31**, in the case where an air-cell battery is employed, and it is necessary to use said cover **31** for the passage of air into the battery compartment, it therefore would have been obvious for one of ordinary skill in the art at the time of the invention to locate the magnet **45** at the bottom or side of the cup-like battery holder, since this alternate location will also operate to secure the battery within the device housing while not blocking the aeration opening for an air-cell battery.

Regarding claim 7, The combination of Reiter, Gnecco and Giannetti, does not clearly teach that the housing is composed of titanium or a titanium alloy. However, it is well known in the art that titanium is a biocompatible material often used for constructing hearing devices intended for implantation. Therefore, it would have been obvious for one of ordinary skill in the art at the time of the invention to construct the housing of Reiter, Gnecco and Giannetti, from titanium, titanium alloy or another metal thereby providing a means for shielding internal electronics from electromagnetic interference, and also having biocompatible characteristics such that the housing's close contact with the wearer's skin will not cause irritation.

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Regarding claim 9, Reiter teaches that the battery compartment further comprises a hole **50** for allowing external access of air to the battery.

4. **Claims 2 and 5** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Reiter et al. US 5,724,431** in view of **Gnecco US 5,640,457** in view of **Giannetti US 5,675,657**, as applied to claim 1 above, and further in view of **Narisawa US 6,041,128**.

Regarding claim 2, The combination of Reiter, Gnecco and Giannetti, fails to clearly teach a battery compartment comprising a watertight seal from the rest of the housing.

In **column 8, lines 43-47**, Narisawa teaches a battery compartment (**see figure 12**) comprising a watertight seal **45** for preventing the entry of moisture into the rest of the housing. It would have been obvious for one of ordinary skill in the art at the time of the invention to modify the teachings of Reiter, Gnecco and Giannetti, per the teachings of Narisawa, thereby constructing the battery compartment of Reiter such that it includes a watertight seal **45**, for the purpose of enabling the use of air-cell batteries in hearing devices wherein sufficient air entry is permitted without the undesired entry of moisture into the device interior.

Regarding claim 5, in **figure 13B**, Narisawa teaches that the housing comprises a first housing component **42** with a battery compartment **40A** being fastened together with a second housing component **40** and an O-ring seal **45** located there between.

5. **Claim 3** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Reiter et al. US 5,724,431** in view of **Gnecco US 5,640,457** and further in view of **Giannetti US 5,675,657**, as applied to **claim 1** above, and further in view of **Meier US 6,574,343**.

Regarding claim 3, The combination of Reiter, Gnecco and Giannetti, does not clearly teach that a water tight film is used to seal the sound exit opening.

In **column 2, lines 55-57**, Meier teaches a device for use in In-ear hearing devices, and further teaches in **column 4, lines 60-62**, that a sound exit opening may be sealed by an acoustically transmitting, water tight film (also see **column 3, lines 53-56**).

It would have been obvious for one of ordinary skill in the art at the time of the invention to provide the sound exit opening of the Reiter device with a sealing film, for the purpose of preventing ear wax and other debris from penetrating the hearing device, **see column 1, lines 41-51, of Meier**.

6. **Claim 4** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Reiter et al. US 5,724,431** in view of **Gnecco US 5,640**, in view of **Giannetti US 5,675,657**, in view of **Narisawa US 6,041,128**, as applied to claim 2 above, and further in view of **Meier US 6,574,343**.

Regarding claim 4, The combination of Reiter, Gnecco, Giannetti and Narisawa, does not clearly teach that a water tight film is used to seal the sound exit opening.

In **column 2, lines 55-57**, Meier teaches a device for use in In-ear hearing devices, and further teaches in **column 4, lines 60-62**, that a sound exit opening may

be sealed by an acoustically transmitting, water tight film (also see **column 3, lines 53-56**).

It would have been obvious for one of ordinary skill in the art at the time of the invention to provide the sound exit opening of the Reiter device with a sealing film, for the purpose of preventing ear wax and other debris from penetrating the hearing device, **see column 1, lines 41-51, of Meier.**

Response to Arguments

7. Applicant's arguments filed 1/5/2006 have been fully considered but they are not persuasive.

Argument With Regard To 35 USC 112 Rejection:

8. The Applicant argues the following: **That The Sound Tube Is Not An External Moving Operational Element, And With Further Reference To The Applicant's Specification On Page 4, Beginning At Line 11, The Applicant Argues That Only Rotatable Potentiometers, Toggle Switches Or Pushbutton(s) Constitute The "External Moving Operational Element" Recited In The Claim:**

This is not a persuasive argument since the features upon which applicant relies (i.e., rotatable potentiometers, toggle switches or pushbuttons) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The Examiner maintains, that since the sound tube **6** is *external* to cylindrical housing **2a,2b**, and *moves* with an applied rotational force, *operating* to transmit sound to the ear canal of the wearer, it fairly constitutes the broadly claimed “external moving operational element” thereby rendering the claim misdescriptive.

9. The Applicant argues that: **There Is No Indication In The Description That The Sound Tube Rotates To Operate After Installation.**

However, it is important to note that the claim does not recite “free of external moving operational elements which continue to move after installation”, as argued. Therefore, as stated previously, the features upon which applicant relies (i.e., movement after installation) are not recited in the rejected claim(s).

Argument With Regard To Claim Rejection 35 USC 103, claims 1,7 and 9:

10. The Applicant argues that **The Screw Driver Adjustable Knob For Controlling Volume Is Clearly A “Moving Operational Element” In Such That A Knob Is A Potentiometer, Or Equivalent, And Reiter Thus Fails Establish A *Prima Facie* Case Of Obviousness Under 35 USC 103.**

The Examiner agrees with the Applicant that screw driver adjustable knob **60**’, taught in **figure 5** of Reiter, constitutes a potentiometer, or equivalent, and reads on “moving operational element”.

However, the screw driver adjustable knob 60" is located internally of the device housing, in such that knob 60" is only rotatable via the insertion of a screw driver. Therefore, **figure 5** of Reiter does in fact anticipate the limitation "free of external moving operational elements", since knob 60" is not externally mounted.

Applicant's arguments with respect to Reiter/Gnecco/Giannetti/Narisawa, all hinge upon the Applicants allegations of the improper reliance upon Reiter as a primary reference. However, as stated above, the Applicant's arguments with respect to Reiter are not found persuasive and therefore, all rejections are maintained.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dionne H. Pendleton whose telephone number is 571-272-7497. The examiner can normally be reached on 9-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sinh Tran can be reached on 571-272-7564. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Dionne Pendleton



HUYEN LE
PRIMARY EXAMINER